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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,725	02/25/2004	Kirk D. Swenson	3896-031736 (P-6004)	2750

32182 7590 05/24/2007  
DAVID W. HIGHET, VP AND CHIEF IP COUNSEL  
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FRANKLIN LAKES, NJ 07414-1880

EXAMINER
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TOWA, RENE T

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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05/24/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/786,725

Applicant(s)

SWENSON ET AL.

Examiner

Rene Towa

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 23-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. This Office action is responsive to an amendment filed March 12, 2007. Claims 1-9 and 23-26 are pending. Claims 10-22 and 27-38 have been cancelled. No claim has been added. Claims 1 and 23 have been amended.

#### ***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollister (US Patent No. 4,982,842) in view of Sweeney et al. (US 5,599,318).

In regards to claim 1, Hollister disclose(s) a holder assembly comprising:

a holder housing 72 capable of receiving a sample collection tube within a rearward end, a forward end of the holder housing 72 including a needle receiving port for receiving a needle cannula 68 therein and an annular skirt extending about the needle receiving port; and

a safety shield 14 pivotably attached to a collar 2b, said collar 2b having an opening therethrough for receiving a needle cannula 68 therethrough, the collar 2b received between the annular skirt 76 and the needle receiving port of the holder housing 72 such that the safety shield 14 is capable of being pivoted over at least a portion of a needle received within the needle receiving port of the holder housing 72,

wherein the safety shield 14 and the collar 2b are rotatable with respect to the holder housing 72 about an axis of the holder housing 72 (see figs. 1A & 3-4).

In regards to claim 2, Hollister disclose(s) a holder assembly wherein the collar 2b is annular (see fig. 4).

In regards to claim 3, Hollister disclose(s) a holder assembly wherein the shield 14 comprises a rearward end, a forward end, a longitudinal opening in the forward end for receiving a needle, and a hanger bar 8 on the rearward end capable of connecting the safety shield 14 to the collar 2b (see fig. 1A).

In regards to claim 4, Hollister disclose(s) a holder assembly wherein the collar 2b comprises a hook arm 12, the hook arm 12 engages the hanger bar 8 for connecting the safety shield 14 to the collar 2b whereby there is an interface fit between the hanger bar 8 and the hook arm 12 (see fig. 1A).

In regards to claim 5, Hollister disclose(s) a holder assembly wherein an outer surface of the collar 2b includes a protrusion 18 and an inner surface of the annular skirt 76 includes a groove 78, the groove 78 on the annular skirt 76 capable of receiving the protrusion 18 on the annular collar 2b, thereby providing an interface fit when the collar 2b is received between the annular skirt 76 and the needle receiving port of the holder housing 72 (see fig. 4).

In regards to claim 6, Hollister disclose(s) a holder assembly wherein the protrusion 18 is annular and extends around the outer surface of the collar 2b and the groove 78 is annular and extends around the inner surface of the annular skirt 76 (see fig. 4).

In regards to claim 9, Hollister disclose(s) a holder assembly wherein the shield 14 and the collar 2b are integral and attached through a living hinge 12 (see figs. 1A & 4).

Hollister discloses a device, as described above, that teaches all the limitations of the claims except Hollister does not expressly disclose an annular skirt, a safety shield and a collar; wherein the safety shield and a collar can be radially rotated to a desired position around the axis without the axial movement of the collar along the axis.

However, Sweeney et al. disclose a device comprising wherein an annular skirt, a safety shield and a collar; wherein the safety shield and a collar can be radially rotated to a desired position around the axis without the axial movement of the collar along the axis (see fig. 18; column 7/lines 15-62).

As such, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Hollister with a safety shield and a collar that can be radially rotated to a desired position around the axis without the axial movement of the collar along the axis similar to that of Sweeney et al. in order to optimally orient the needle assembly during insertion (see Sweeney et al., column 7/lines 43-62).

4. Claims 7 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollister ('842) in view of Sweeney et al. ('318) further in view of Cameron (US Patent No. 5,197,954).

In regards to claim 23, Hollister disclose(s) a holder assembly comprising:

a holder housing capable of receiving a sample collection tube within a rearward end, a forward end of the holder housing including a needle receiving port for receiving a needle cannula 68 therein, the holder housing having an annular skirt extending from the forward end, and

a collar 2b which attaches to the forward end of the holder housing, the collar 2b having a hook arm 12 for connection of a safety shield 14 (see figs. 1A, 3 & 4).

In regards to claim 24, Hollister disclose(s) a holder assembly wherein the collar 2b is rotatable about an axis of the holder housing (see fig. 3).

In regards to claim 25, Hollister disclose(s) a holder assembly wherein the collar 2b further comprises an interior opening for receiving a needle cannula 68 therein (see figs. 1A & 3-4).

In regards to claim 26, Hollister disclose(s) a holder assembly wherein the interior opening includes structure for engagement with corresponding mating structure on a needle cannula assembly (see figs. 1A & 3-4).

Hollister discloses a device, as described above, that teaches all the limitations of the claims except Hollister does not expressly disclose an annular skirt, a safety shield and a collar; wherein the safety shield and a collar can be radially rotated to a desired position around the axis without the axial movement of the collar along the axis.

However, Sweeney et al. disclose a device comprising wherein an annular skirt, a safety shield and a collar; wherein the safety shield and a collar can be radially rotated to a desired position around the axis without the axial movement of the collar along the axis (see fig. 18; column 7/lines 15-62).

As such, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Hollister with a safety shield and a collar that can be radially rotated to a desired position around the axis without the axial movement of the collar along the axis similar to that of Sweeney et al. in order to optimally orient the needle assembly during insertion (see Sweeney et al., column 7/lines 43-62).

Hollister as modified by Sweeney et al. discloses an assembly, as described above, that teaches all the limitations of the claims except Hollister as modified by Sweeney et al. does not explicitly teach an annular skirt that substantially encloses an open end of the hook arm.

However, Cameron discloses a holder assembly wherein an annular skirt 72 abuts a hook arm 84 when a holder housing 12 and a collar 72 are in an attached position; wherein the annular skirt substantially encloses an open end of a hook arm (see fig. 5).

It would have been obvious to one of ordinary skill in the art the time applicant's invention was made to provide a device similar to that of Hollister as modified by Sweeney et al. with an abutment structure similar to that of Cameron in order to releasably lock or firmly hold the base of the collar against the holder housing (see Cameron, column 7/lines 1-8 & 13-17).

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hollister ('541) in view of Sweeney et al. ('318) further in view of Cosme (US Patent No. 6,077,253).

Hollister as modified by Sweeney et al. discloses an apparatus, as described above, that teaches all the limitations of the claim except Hollister does not teach a plurality of slits.

However, Cosme discloses a holder assembly comprising a plurality of slits 16 (see fig. 3).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an apparatus similar to that of Hollister as modified by Sweeney et al. with slits similar to those of Cosme in order to restrain rotational movement of the collar (see Cosme, column 3/lines 1-12).

### ***Response to Arguments***

6. Applicant's arguments filed March 12, 2007 have been fully considered but are moot in view of the new grounds of rejection(s).

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any



Art Unit: 3736

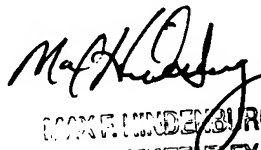
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT

  
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